

COURSE 3, TUTORIAL 4

AN OVERVIEW OF THE HHS SBIR/STTR SOLICITATION PROCESS



The Department of Health and Human Services provides both grants and contracts. However, almost ninety-five percent of HHS SBIR and STTR awards are made as grants primarily through the National Institutes of Health or NIH. NIH is the largest granting organization participating in the SBIR and STTR programs. Its budget for FY16 is \$763M for SBIR and \$114M for STTR. These programs are both large and unique.

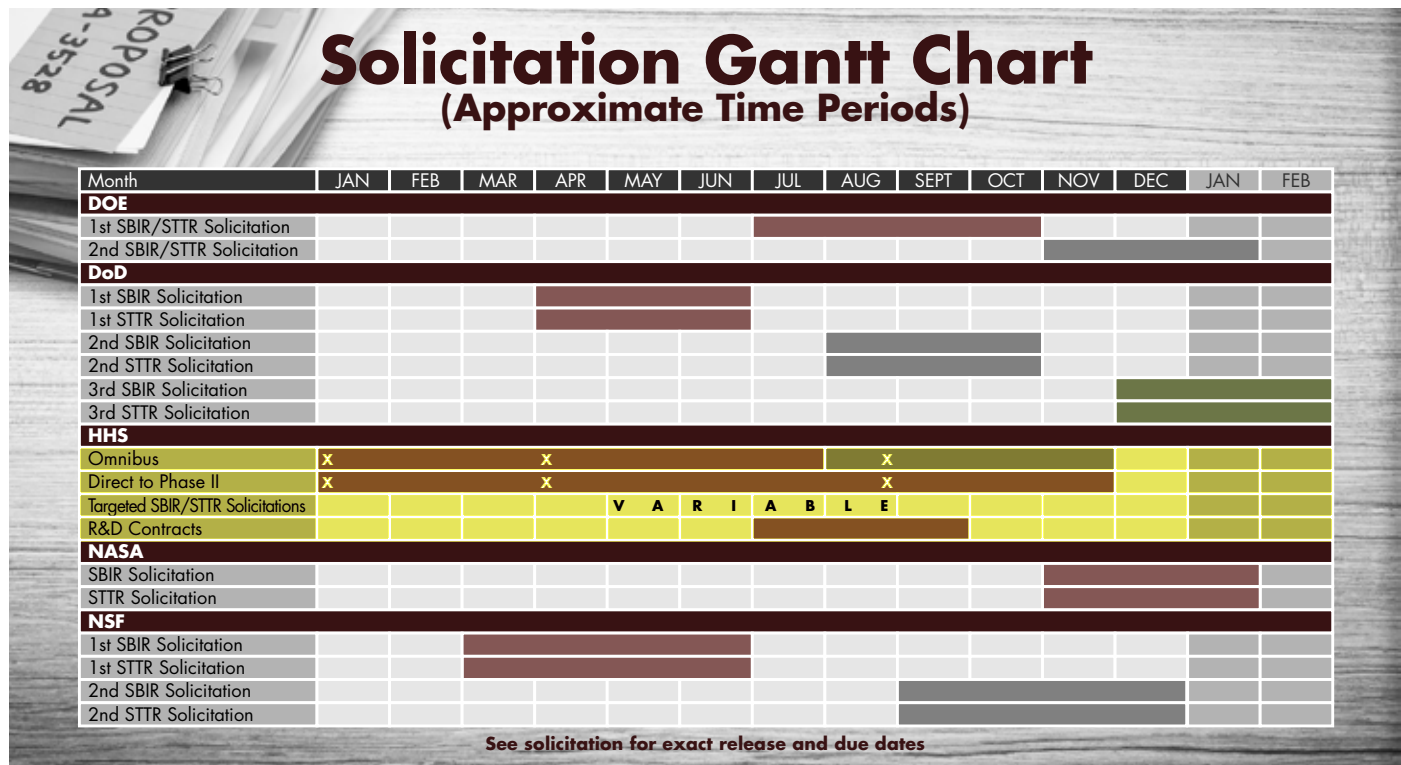
REACH OUT TO INSTITUTE CONTACTS

To understand the funding mechanisms used by HHS, the recommended starting point is the [NIH SBIR/STTR funding page](#). In the preliminary text you will find a link to the SF424 (R&R) SBIR/STTR Application Guide, as well as a companion document called the Annotated SBIR/STTR Form Set. I suggest that you download these to your desktop right away and put them in a folder. Navigating further down the page you come to a collection of five icons, each containing the name of a solicitation. In this orientation we will focus uniquely on the first – the 2015 SBIR and STTR Omnibus Grant Solicitation of the NIH, CDC, FDA and ACF.

Let's closely examine each item associated with the Omnibus solicitation before we delve into the Topics Document and the Funding Opportunity Announcements. The abbreviation PA stands for **Parent Announcements**. These are broad funding opportunity announcements for specific activities or types of research. There is one PA for the SBIR program and another

for the STTR program. Both of these Funding Opportunity Announcements or FOA are for investigator-initiated applications. There is also a Topics Document and another entitled "2015 SBA approved topics-list for budget waivers." We'll discuss all of these in a moment. There is also a hyperlink to [NIH SBIR/STTR Grant Forms](#). It's easy to navigate to everything that you may need from this one page. There is also a reminder on the right hand side of the grey box indicating that there are THREE standard receipt dates for proposals in response to the Parent Announcements. The option to submit an application on one of three receipt dates is a unique feature of the HHS SBIR and STTR programs.

Download the Topics document now to your desktop. Although the hyperlink refers to this as the 2015 Program Descriptions and Research Topics Document – it is actually the Omnibus Solicitation as noted on the cover page. You will also notice that the cover page indicates that this document is for both the SBIR and STTR programs. In the program description sec-



tion it clarifies that NIH will accept and consider SBIR and STTR grant applications in any area within the mission of the awarding components – that is the **Institutes and Centers or ICs** identified in the Omnibus Solicitation. Unlike other agencies that often designate unique topics for the SBIR or STTR program – all NIH topics can be addressed using either the SBIR or STTR program.

REACH OUT TO INSTITUTE CONTACTS

Let's look at the first Institute in the solicitation – the National Institute of Aging or NIA. The opening paragraph lists the four divisions of NIA and then provides a brief description of the areas of interest for each Division. The cognizant contact person's name, phone number and e-mail are listed throughout. You are encouraged to reach out to the contact to discuss your research interests throughout the entire application, review and award process. A list of the HHS SBIR/STTR Agency Contacts is always readily available, as well as the contact information for the NIH SBIR/STTR program office. You are reminded that there is nothing more important to your success with NIH than to reach out to the NIH contacts early and often. This is especially important during the planning stages when you should discuss your research interests to determine if they are well aligned with the needs of the Institute or Center. Contacts can readily direct

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you to the appropriate institute, if your research idea does not fit with their mission.

BUDGET CAPS

This document is usually about 200 pages in length and is rich with descriptions of the ICs research interests. Each Institute or Center also includes comments regarding unique SBIR/STTR guidelines that may pertain to their organization. For example, budget limits, adjustments to duration of awards, or related

solicitations may be mentioned. One item that you may often see referenced is SBA budget caps. There is a document entitled SBA Approved Topics List for Budget Waivers on the Funding page. The SBIR and STTR programs do have statutory budget limits. However, given the costs associated with maturing medical technologies – the Small Business Administration has made exceptions for a number of NIH SBIR and STTR topics.

The topic areas that have a waiver are identified on the NIH SBIR/STTR funding page in the document we just referenced. Companies that wish to propose budgets in excess of the statutory limits are strongly encouraged to contact NIH program officials prior to submitting any award budget in excess of the statutory amounts.



Let's go back to the NIH SBIR/STTR Funding page and look at the SBIR Omnibus Funding Opportunity Announcement link. When you navigate to PA-15-269 you are presented with a considerable amount of information. If this is the first time that you have visited this page, you may be overwhelmed by the number of hyperlinks. Much of the information provided are links to related organizations, and documents. For example, the first two sections entitled Participating Organizations and Components of Participating Organizations is a compilation of the links to the agencies participating in this Funding Opportunity Announcement. Navigate further down the page until you come to Part 2 – Full Text of the Announcement. This is the section that you need to explore in detail. An important companion document, it is one that was recommended to download at the outset. Open the file that you downloaded previously entitled SF424 (R&R) SBIR/STTR Application Guide. On the cover you see the acronym PHS – this stands for Public Health Service. There's a number of unique characteristics of the HHS program highlighted in this document. Let's look at a number of them – starting with eligibility.

VENTURE CAPITAL OPERATING COMPANIES

In Section 1.3.4 a unique statement is added regarding eligibility. It states that SBCs, that is Small Business Concerns - that are majority-owned by multiple venture capital operating companies or VCOCs, hedge funds or private equity firms are NOW eligible to apply to the NIH SBIR program at this time for any NIH SBIR funding opportunity announcement issued after January 28, 2013. This is unique to NIH, CDC, and the Department of Energy's Advanced Research Projects Agency. The other agencies participating in the SBIR program have not opted to participate in the Majority VC ownership authority. Please note that within HHS, both the FDA and ACF SBIR program, as well as the NIH STTR program do not participate in this authority.

GRANTS.GOV AND ERA COMMONS

In another section of this document, the method of submitting proposals in response to this Omnibus solicitation is described. You will need to submit your proposal through Grants.gov and must also complete a one time registration with eRA Commons. It is recommended that you register with eRA Commons at least 6 weeks prior to the submittal date of a Grants.gov submission. The proposal that you will submit to NIH is actually a collection of forms and documents that you will upload into Grants.gov as an application. In order to understand the structure of your application, you should download the appropriate grants package from grants.gov as early as possible. The following table indicates the types of forms that are required to complete the application. This approach to proposal submission is unique to granting agencies that utilize grants.gov. For the first time applicant, anticipate that it will take considerable time to understand the structure and how to prepare a compelling application.

Another unique feature of working with NIH is the resubmission of applications. To learn more about the resubmission option, review the section in the R&R Guide called "Resubmission Applications".

In this tutorial we have touched briefly on only one of the HHS solicitations – the SBIR/STTR Omnibus Solicitation for NIH, CDC, FDA, and ACF. It will take you time to learn how to write winning proposals in response to the many HHS opportunities. The best way to increase the likelihood of success is to reach out the HHS SBIR/STTR program office; as well as the numerous Points of Contact within each of the Institutes and Centers. Be sure to take advantage of the opportunity to communicate frequently with agency personnel who are positioned to assist in paving a straighter road to success.

HHS SBIR/STTR RESOURCES

HHS SBIR/STTR Agency Contact Information

<https://sbir.nih.gov/engage/ic-contacts>

Life Science Contacts by State

<https://sbir.nih.gov/resources/lifescience-state-contacts>

NIH SBIR/STTR Funding

<https://sbir.nih.gov/funding>

NIH SBIR/STTR Application Process Infographic

<https://sbir.nih.gov/infographic>

SBIR/STTR Application Guide for NIH and Other PHS Agencies

http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_SBIR_STTR_VerC.pdf

Small Business Grant Applications: Annotated SF424 (R&R) Form Set

http://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_FORMS-C_SmallBus-1.pdf

eRA SERVICE DESK

<https://sbir.nih.gov/engage/eRA-commons>

Phone: 1-866-504-9552, Hours: Mon–Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)